

June 22, 2006

Letter From Dr. Everts (Pfizer) to Dr. Katz (FDA)

Pfizer Global Pharmaceuticals

22 June 2006

Russell G. Katz, MD
Division Director
Division of Neurology
Product Evaluation-230
Center for Evaluation and Research
Food and Drug Administration
5000-48 Anzio Road
Beltsville, Maryland 20705-1266

RE: NEURONTIN®(gabapentin) capsules NDA 20-235
NEURONTIN®(gabapentin) tablets NDA 20-882*
NEURONTIN®(gabapentin) oral solution NDA 21-129*

Request for Information - Response to FDA suicidality request

Dear Dr. Katz:

Reference is made to NDA 20-235, NDA 20-882 and NDA 21-129 for Neurontin®(gabapentin) capsules, tablets and oral solution (respectively).

Reference is also made to "possibly suicidal" and correspondence On 20 April 2006 criteria of ultimate subjects; patient and was used as an example with an explicit gabapentin study instructions to exclude.

Further reference is dated 20 April 2006.

Confidential

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Category	Gabapentin (N=5194) n (%)	Placebo (N=2682) n (%)	Active Control (N=661) n (%)	Low-Dose Placebo (N=292) n (%)
Completed suicide (code 1)	0 (0.000)	0 (0.000)	0 (0.000)	0 (0.000)
Suicide attempt (code 2)	0 (0.000)	0 (0.000)	0 (0.000)	0 (0.000)
Preparatory acts towards imminent suicidal behavior (code 3)	0 (0.000)	0 (0.000)	0 (0.000)	0 (0.000)
Self-injurious behavior, intent unknown (code 4)	1 (0.019)	0 (0.000)	0 (0.000)	0 (0.000)
Suicidal ideation (code 5)	2 (0.039)	1 (0.037)	0 (0.000)	0 (0.000)
Not enough information (code 6)	3 (0.058)	3 (0.112)	0 (0.000)	0 (0.000)
- Fatal (code 6a)	1 (0.019)	0 (0.000)	0 (0.000)	0 (0.000)
- Non-fatal (code 6b)	2 (0.039)	3 (0.112)	0 (0.000)	0 (0.000)

Confidential

Pfizer MEverts 0125704

Mr. Smith's Pain Complaints

1988

Dr. Tom Nesbitt

- Rectal **pain** with radiation, began after knee surgery

Spalding & Nesbitt Urology Clinic, 000006-623NUC-00027

1989

Dr. James Cato

- Hand tightness; decreased grip
- Pelvic **pain**

Heritage Medical Associates, 000006-42HMA-00016

Dr. Stewart F. Stowers

- Right heel **pain**; right knee **pain**
- Bilateral knee **pain**
- Right hip **pain**
- Suprapubic **pain** [groin area]

Nashville Orthopedic Associates, 000006-694QC-00075

1990

Dr. Stewart F. Stowers

- Left hip **pain** extending to groin

Nashville Orthopedic Associates, 000006-694QC-00074

Dr. James Cato

- Back **pain**; upper abdominal burning; tiredness
- Left jaw and ear pressure/ soreness; left facial numbness

Heritage Medical Associates, 000006-42HMA-00017

Dr. Tom Nesbitt

- Testicular **pain**

Spalding & Nesbitt Urology Clinic, 000006-623NUC-00025

Dr. David M. Dyer

- Chronic right groin/ testicular **pain**

00006-623NUC-00065

1991

Dr. David M. Dyer

- Left groin **pain**

000006-623NUC-00054

Dr. James Cato

- Left jaw, throat, and ear pressure
- Left shoulder complaints; left hip soreness

Heritage Medical Associates, 000006-IPRD-00015-16

1992

Dr. Michael Santi

- Chronic abdominal **pain**

Colon & Rectal Surgery Associates, 000006-48CRSA-0009

1993

Dr. Stewart F. Stowers

- Severe left knee problems; **pain** in left ankle

Nashville Orthopedic Associates, 000006-694MA-00071

Dr. James Cato

- Swelling in hands and ankles; left knee problems
- Tenderness in left ribs

Heritage Medical Associates, 000006-42HMA-00020

1994

Dr. Stewart F. Stowers

- Left knee tightness; **pain** in left ankle

Nashville Orthopedic Associates, 000006-694QC-00064

1995

Dr. James Cato

- Numbness to left side of face/ eye; left tooth problems
- Left chest soreness

Heritage Medical Associates, 000006-42HMA-00223

Dr. David M. Dyer

- Left groin **pain**

000006-30HMA-00072

Dr. Stewart F. Stowers

- Left knee ache

Tennessee Orthopedic Associates, 000006-694QC-00063

1996

Dr. Stewart F. Stowers

- Severe right hip **pain**

Tennessee Orthopedic Associates, 000006-694QC-00062

Dr. Eugene M. Regan Jr.

- Right hip and groin **pain**; significant limp
- Difficulty sleeping because of hip **pain**
- Left shoulder problems

Tennessee Orthopedic Alliance, 000006-694QC-00061

Tennessee Orthopedic Alliance, 000006-694QC-00060

Tennessee Orthopedic Alliance, 000006-32TDA-00047

Vicki Bryant, P.T.

- Low back **pain**; foot symptoms

000006-694QC-00133

Dr. James Cato

- Lower abdominal **pain**
- Chest **pain**; arm tingling; numbness to left side of face

Heritage Medical Associates, 000006-30HMA-00030

1997

Dr. Tom Nesbitt

- Difficulty urinating, with burning

Spalding & Nesbitt Urology Clinic, 000006-623NUC-00021

RAH

- Lower abdominal **pain**
- Pressure in rectum, scrotum, and groin

Colon & Rectal Surgery Associates, 000006-48CRSA-00096

Dr. Eugene M. Regan Jr.

- Right knee **pain**; low back **pain**; left knee tightness

Tennessee Orthopedic Alliance, 000006-32TDA-00046

Dr. Tom Nesbitt

- Testicular **pain**; erectile discomfort

Spalding & Nesbitt Urology Clinic, 000006-623NUC-00018

1998

Dr. James Cato

- Chest discomfort; facial soreness

Heritage Medical Associates, 000006-30HMA-00032-33

Dr. Eugene M. Regan Jr.

- Left ankle **pain**
- Increasing right knee **pain** with significant limp

Tennessee Orthopedic Alliance, 000006-32TDA-00044-45

1999

Dr. James Cato

- Left shoulder soreness and biceps tenderness

Heritage Medical Associates, 000006-42HMA-00016-117

Dr. Stewart F. Stowers

- Right knee stiffness

Tennessee Orthopedic Associates, 000006-32TDA-00023

Baptist Hospital ER

- Rib **pain**; shoulder **pain**; chest **pain**; abdominal **pain**

000006-738AH-00019

Mr. Smith's Pain Complaints

2000

2001

2002

2003

2004

Dr. Stewart F. Stowers

- Left sacroiliac **pain** [hip/buttocks region]
Tennessee Orthopedic Alliance, 000006-69AQC-00022
- Left knee flare-up; ankle soreness
Tennessee Orthopedic Alliance, 000006-69AQC-00023

Dr. James Cato

- Left knee **pain**
Heritage Medical Associates, 000006-30HMA-00042-43

Dr. Tom Nesbitt

- Groin **pain**
Spaulding & Nesbitt Urology Clinic, 000006-625NUC-00014

Dr. Stewart F. Stowers

- Left shoulder **pain**
Tennessee Orthopedic Alliance, 000006-32TOA-00012
- Left knee **pain**
Tennessee Orthopedic Alliance, 000006-69AQC-00016
- Left knee and left ankle **pain**
Tennessee Orthopedic Alliance, 000006-69AQC-00015

Dr. James Cato

- Pain across shoulder blades
Heritage Medical Associates, 000006-30HMA-00048-49
- Neck **pain** and stiffness; vertigo
Heritage Medical Associates, 000006-30HMA-00050-51
- Neck/shoulder **pain** and spasms; rib soreness; poor sleep
Heritage Medical Associates, 000006-30HMA-00052-53
- Chest soreness
Heritage Medical Associates, 000006-30HMA-00054-55

Dr. Gregory Mowery

- Vertigo; balance problems
Otolaryngology Associates of Tennessee, 000006-11DAT-00001

Dr. Tom Nesbitt

- Groin **pain**
Spaulding & Nesbitt Urology Clinic, 000006-625NUC-00013

Dr. Stewart F. Stowers

- Left shoulder **pain** and weakness
Tennessee Orthopedic Alliance, 000006-32TOA-00021
- Left knee **pain**
Tennessee Orthopedic Alliance, 000006-32TOA-00021

Dr. Tom Nesbitt

- Intermittent groin **pain**
Spaulding & Nesbitt Urology Clinic, 000006-625NUC-00012

Dr. Stuart E. Smith

- Global **pain** and stiffness
Tennessee Orthopedic Alliance, 000006-69AQC-00008

Dr. Jeffrey P. Lawrence

- Left shoulder **pain** and inability to lift arm
Premier Orthopedics & Sports Medicine, 000006-120POS-00007

Dr. Tom Nesbitt

- Intermittent groin **pain; pain** with urination
Spaulding & Nesbitt Urology Clinic, 000006-625NUC-00011
- Leg and spine **pain**
Spaulding & Nesbitt Urology Clinic, 000006-625NUC-00028

Dr. Michael Santini

- Lower abdominal **pain**
Colon & Rectal Surgery Associates, 000006-48CRSA-00005

Dr. James Cato

- Sore joints; bladder/prostate symptoms
Heritage Medical Associates, 000006-30HMA-00056-59

Dr. Paul R. McCombs III

- Pain in all joints; not sleeping
Heritage Medical Associates, 000006-30HMA-00060-62

Dr. Stuart E. Smith

- Joint **pain**; back **pain/numbness/tingling**
Heritage Medical Associates, 000006-42HMA-00140-141

Dr. Jeffrey L. Herring

- Anxiety and depression
Heritage Medical Associates, 000006-30HMA-00065-64

Dr. Michel McDonald

- Nerve prickling down back; **pain** in legs, knees, ankles after lumbar surgery
Heritage Medical Associates, 000006-30HMA-00063-64

Dr. Carl Hampf

- Arthritis
Vanderbilt University Medical Center, 000006-49VUM-00009

Dr. Tom Nesbitt

- Hip, back, and bilateral leg **pain** and paresthesias
Tennessee Orthopedic Alliance, 000006-69AQC-00006

Dr. Powers Chiropractic Clinic

- Bilateral hip and knee **pain**
Tennessee Orthopedic Alliance, 000006-69AQC-00006

Dr. Jeffrey L. Herring

- Frequent joint **pain**, even in replaced joints
000006-1PRD-00162-165

Dr. Frank M. Berklaich

- Depressed because of **pain** and lack of sleep
000006-1PRD-00162-165

Dr. William A. Shell

- Significant low back and bilateral leg **pain**
000006-18FMB-00002-3

Dr. James Cato

- Numbness and pins/needles in both legs
000006-18FMB-00002-3

Dr. Michael Santini

- Weakness and difficulty walking
000006-18FMB-00002-3

Dr. Edward S. Mackey

- Sleep impaired by **pain**
000006-18FMB-00002-3

Dr. Pam Krancer, R.N., C.S., CRNP

- Diarrhea due to anxiety and **pain**
000006-52FMB-00041

Dr. Paul R. McCombs III

- Back and bilateral leg **pain**
Neurosurgical Associates, 000006-34NEA-00021

Dr. Stuart E. Smith

- Back and bilateral leg **pain** symptoms unchanged
Neurosurgical Associates, 000006-34NEA-00020

Dr. Michel McDonald

- Severe low back and leg **pain** after lumbar surgery
Neurosurgical Associates, 000006-1PRD-00405

Dr. Tom Nesbitt

- Continues with **pain** and is very concerned
Neurosurgical Associates, 000006-1PRD-00406

Dr. Edward S. Mackey

- Wishes he could die because of **pain** and depression
Neurosurgical Associates, 000006-1PRD-00408

Dr. Pam Krancer, R.N., C.S., CRNP

- Increased leg **pain** after lumbar surgery
Neurosurgical Associates, 000006-34NEA-00021

Dr. Jeffrey L. Herring

- Right ankle **pain**
Tennessee Orthopedic Alliance, 000006-69AQC-00003

Dr. Powers Chiropractic Clinic

- Right shoulder **pain**
000006-125MAC-00002-3

Dr. William A. Shell

- Difficulty urinating since back surgery
Spaulding & Nesbitt Urology Clinic, 000006-625NUC-00009

Dr. Pam Krancer, R.N., C.S., CRNP

- Bilateral leg **pain** radiating from buttocks, perineal area [groin], and thigh to knees
Neurosurgical Associates, 000006-34NEA-00003

Physical Therapy Evaluation

- Pain/tingling from lumbar spine to ankle; left groin **pain**
University Medical Center, 000006-35UWC-00058

Dr. James Cato

- Pain in knees and ankles; **pain** excruciating and sharp
University Medical Center, 000006-35UWC-00076

Mr. Smith's Surgeries

1984

Tonsillectomy

Dr. Dale Beck, 000006-1PRD-00025-26

1985

Right knee surgery for torn cartilage

Dr. John Brunn, 000006-1PRD-00025-26

March 10, 1988

Left knee surgery for torn cartilage

Dr. Burton Elrod, 000006-1PRD-00025-26

January 3, 1990

Transurethral resection of prostate

Dr. Tom Nesbitt, 000006-625NUC-00048-49

May 29, 1991

Left inguinal hernia repair

Dr. David M. Dyer, 000006-625NUC-00053

November 16, 1993

Total left knee replacement

Dr. Stewart F. Stowers, 000006-69AQC-00067

November 20, 1995

Left inguinal hernia repair with mesh prosthesis

Dr. David M. Dyer, 000006-30HMA-00072

May 2, 1996

Total right hip replacement

Dr. Eugene M. Regan Jr., 000006-85BAH-00197-198

May 11, 1998

Incision of bladder neck contracture

Dr. Tom Nesbitt, 000006-85BAH-00405-406

June 19, 1998

Total right knee replacement

Dr. Eugene M. Regan Jr., 000006-78BAH-00009-11

March 3, 2003

Lumbar epidural steroid injection under fluoroscopy

000006-15PRR-00002

March 21, 2003

Lumbar epidural steroid injection under fluoroscopy

000006-15PRR-00001

April 1, 2003

Lumbar laminectomy with fusion at three levels: L3-L4, L4-L5, and L5-S1

Dr. Paul R. McCombs III, 000006-64CMD-00119

September 24, 2003

Micrographic surgery to remove basal cell carcinoma from nose

Dr. Thomas Stasko, 000006-39WBH-00026-27

December 11, 2003

Cataract extraction with lens implantation in the left eye

Dr. Kaswinkel, 000006-47LVC-00016

1980s

1990s

2000s

February 27, 2003

Neurological Surgeons Questionnaire

12/23/2002 1:24 PM NEUROLOGICAL SURGEON NO. 964 P. 5
1/22/2003 1:27PM NO. 160 P. 5
131683-9

NEUROLOGICAL SURGEON

New Patient Medical Questionnaire

This is a simple form and we appreciate its length.

It is important for you to describe yourself & tell us exactly what is wrong with you.

Name: Richard H Smith Address: 10045 Davis Run Rd City: Wichita Falls State: TX Zip: 76301 County: Montgomery

Primary Doctor and address: Dr. Paul R. Goff 2500 University Ave 37014

Doctor you are seeing today: Dr. Hough Doctor's office: 1010 S. 10th St.

Do you have a long list? Do you have an educated detective? If yes there is a long list or an educated detective please provide us with it as soon as possible.

Present Problem:

1. What symptoms do you want the Doctor today? Please describe your symptoms and length of time you have had them.

Sore back in hip area, down back of thighs, down into buttocks, sometimes out at spine
Tingling - Head to尾骨
Try to sleep, but can't because of pain, back down on floor

2. How long has this problem been? 8 weeks Day: Mon Month: Feb

12/23/2002 1:24 PM NEUROLOGICAL SURGEON NO. 964 P. 11
1/22/2003 1:27PM NO. 160 P. 8
131683-9 484

Migraine headache

Frequent episodes of joint pain Last 8 weeks - Burns in replaced joints

Severe back pain

Constant or leg pain with walking

GENERAL

Blacks or blisters easily

Any change in mood Depressed because of pain + back at sleep

Trouble sleeping New date given out. Hydrocodone

Explain your new date situation

Any change in mood Depressed because of pain + back at sleep

HIGHLY CONFIDENTIAL 000006-1PRD-00162

Report disease							
High blood pressure	X	X					
Stroke							
Kidney disease							
Breast cancer			X		X		
Prostate cancer							
Colon cancer	X						
Psychiatric illness							
Anemia							

Social History

Do you use tobacco? No How much and how long?

Do you use alcohol? No How much and how long?

Education? High School

Vocation? Repair office equipment Bill working? Retired

Are you exposed to toxins? No

Physician's Signature DH Date 2/27/03

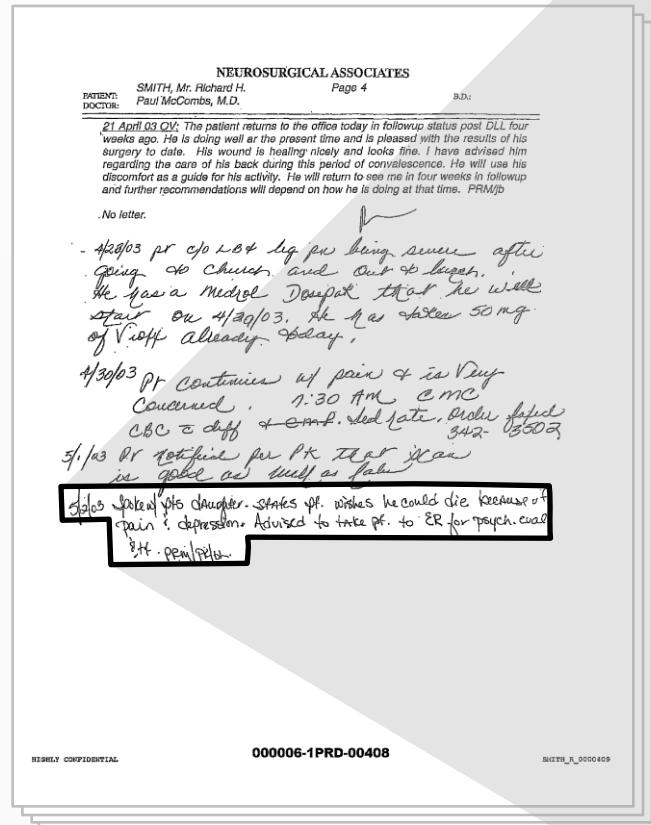
HIGHLY CONFIDENTIAL

000006-1PRD-00165

SMITH_R_0000166

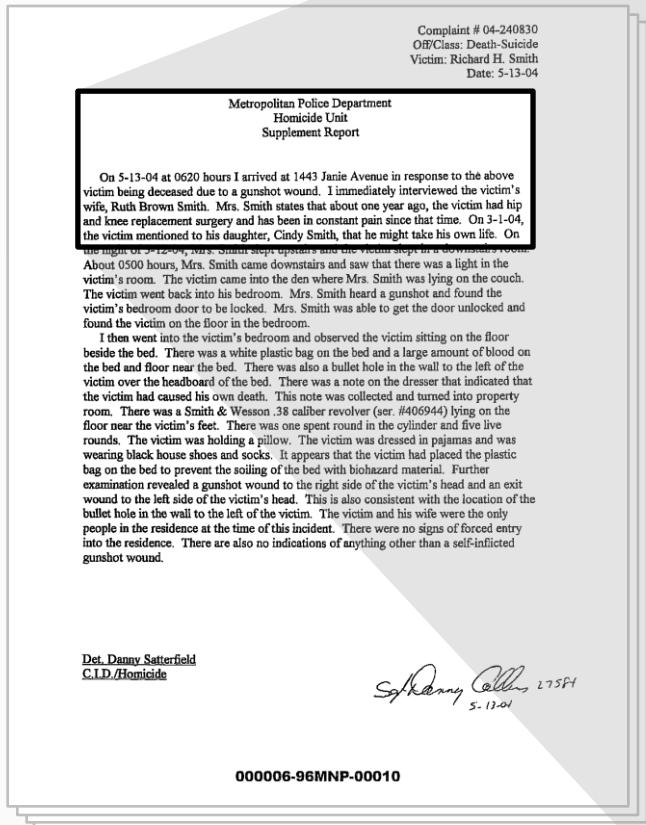
May 2, 2003

Neurosurgical Associates Notes – Dr. McCombs



Spoke w[ith] p[atiens]t's daughter. States p[atiens]t wishes he could die because of pain and depression. Advised to take p[atiens]t to ER for psych. eval and tx [treatment].

May 13, 2004 Police Report



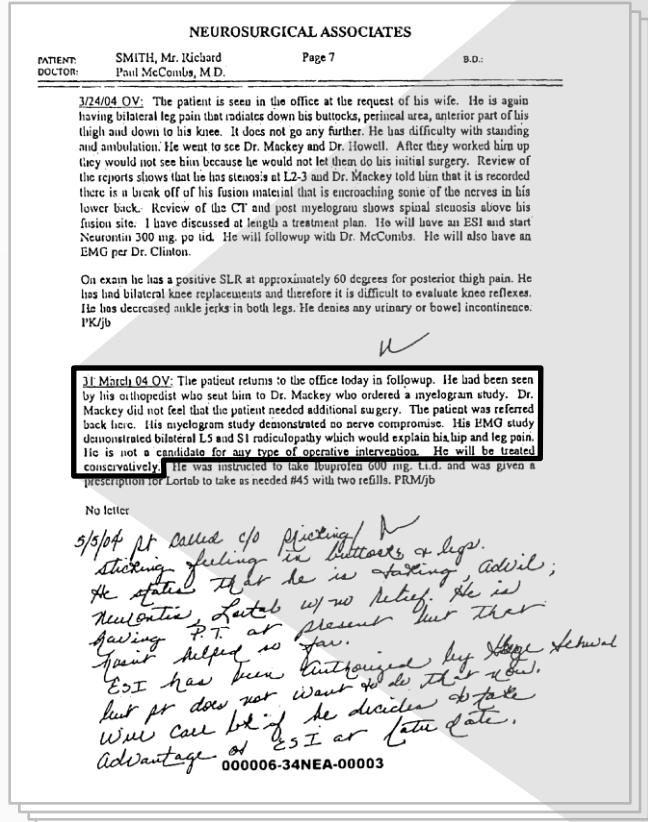
Metropolitan Police Department

* * *

On 3-1-04, the victim mentioned to his daughter, Cindy Smith, that he might take his own life.

March 31, 2004

Dr. McCombs's Notes



31 March 04 OV: ... He had been seen by his orthopedist who sent him to Dr. Mackey who ordered a myelogram study. Dr. Mackey did not feel that the patient needed additional surgery. The patient was referred back here. His myelogram study demonstrated no nerve compromise. His EMG study demonstrated bilateral L5 and S1 radiculopathy which would explain hip and leg pain. He is not a candidate for any type of operative intervention. ... He is not a candidate for any type of operative intervention. He will be treated conservatively. ... He is not a candidate for any type of operative intervention. He will be treated conservatively.

Pain has taken over my Mind & Body

I need Back Surgery

Left & Right Rotator Cuffs

Right Bicep Torn

Back Surgery to Correct Pain in Legs

Forgive me, I cannot go on like this!

I cannot have my body, the temple
of the Holy Spirit cut on anymore

I have talked to God almighty and

He understands,

Mr. Smith's Diagnoses

1987

Diverticulitis 000006-48CRSA-00008

1988

Benign prostatic hypertrophy with prostatic calcification 000006-625NUC-00027

1989

Upper respiratory infection/otitis (left ear) 000006-42HMA-00215

Bilateral ulnar nerve entrapment 000006-1PRD-00009

Plantar fasciitis (right foot) 000006-69AQG-00077

Degenerative disease (right knee) 000006-69AQG-00077

Prostatitis 000006-42HMA-00216

Greater trochanteric bursitis (right hip) 000006-69AQG-00076

Possible osteitis pubis 000006-69AQG-00075

Degenerative activity (right ankle and bilateral knees) (per bone scan) 000006-13ODE-00001

1990

Benign prostatic hypertrophy and chronic prostatitis 000006-625NUC-00048-49

Acute iliopsoas strain (left hip) 000006-69AQG-00074

Acid peptic symptoms secondary to ansaid 000006-42HMA-00217

Left temporomandibular joint symptoms 000006-1PRD-00013

Musculoskeletal strain/tendonitis (right groin) 000006-625NUC-00055

Left inguinal hernia 000006-625NUC-00055

1991

Upper respiratory infection/bronchitis 000006-1PRD-00015

Left inguinal hernia 000006-625NUC-00054

Prostatitis 000006-1PRD-00017

Blood in urine 000006-625NUC-00024

Allergy to Cipro 000006-625NUC-00024

1992

Prostatic calcification 000006-625NUC-00024

Patellofemoral osteoarthritis (knee) 000006-69AQG-00072

Degenerative arthritis (both knees) 000006-69AQG-00073

1993

Synovitis (left ankle) 000006-69AQG-00071

Severe osteoarthritis (left knee) 000006-69AQG-00071

Degenerative joint disease (left knee) 000006-42HMA-00220

Musculoskeletal pain (left chest) 000006-1PRD-00002

1994

Osteoarthritis (left ankle) 000006-69AQG-00064

1995

Folliculitis 000006-42HMA-00222

Maxillary irritation 000006-1PRD-00002

Muscular chest pain 000006-42HMA-00223

Recurrent left inguinal hernia 000006-30HMA-00072

End-stage osteoarthritis (right knee) 000006-69AQG-00063

Patellofemoral disease 000006-69AQG-00063

1996

Severe osteoarthritis (right hip) 000006-69AQG-00062

Complete loss of articular cartilage (right hip) 000006-69AQG-00061

Loss of bone stock (right hip) 000006-69AQG-00061

Complete loss of articular cartilage (medial compartment of right knee) 000006-69AQG-00061

Loss of bone stock (right knee) 000006-69AQG-00061

Degenerative joint disease (right hip) 000006-30HMA-00026

Soft tissue strain (abdomen) 000006-30HMA-00029

Musculoskeletal chest pain 000006-30HMA-00030

Intermittent entrapment (left shoulder) 000006-32TOA-00047

Bronchitis 000006-30HMA-00031

1997

Diverticulitis 000006-48CRSA-00006

Arthritic changes (lumbar spine and left hip) 000006-32TOA-00046

Complete loss of articular cartilage (medial compartment of right knee) 000006-32TOA-00046

Loss of bone stock (right knee) 000006-32TOA-00046

Patellofemoral changes (right knee) 000006-32TOA-00046

Benign prostatic hypertrophy and chronic prostatitis 000006-625NUC-00018

1998

Herpes simplex virus I 000006-30HMA-00032-33

Severe bladder neck contracture 000006-625NUC-00017

Severely symptomatic osteoarthritis (right knee) 000006-85BAH-00640-641

Acid peptic disease, perhaps aspirin-related 000006-30HMA-00034-35

Lumbar spondylosis 000006-32TOA-00024

Internal hemorrhoids 000006-48CRSA-00006

1999

Tendonitis (left shoulder) 000006-30HMA-00036-37

Benign prostatic hypertrophy 000006-625NUC-00015

Acute chest pain/abdominal pain 000006-78BAH-00019

2000

Sliding hiatal hernia with gastroesophageal reflux and poor peristalsis of esophagus 000006-42HMA-00159

Lumbar syndrome 000006-69AQG-00022

Pelvic pain and diverticulitis 000006-30HMA-00044-45

Benign prostatic hypertrophy 000006-625NUC-00014

Groin pain secondary to scar tissue from hernia repair 000006-625NUC-00014

Viral upper respiratory infection 000006-30HMA-00046-47

2001

Rotator cuff tear (left shoulder) 000006-32TOA-00022

Degenerative joint disease (spine) 000006-30HMA-00048-49

Vertigo 000006-30HMA-00050-51

Degenerative joint disease 000006-30HMA-00050-51

Degenerative arthritic changes (cervical spine) 000006-42HMA-00156

Arthralgias, sleep disorder; questionable fibromyalgia 000006-30HMA-00052-53

Eustachian tube dysfunction; disequilibrium 000006-11OAT-00001

Groin pain secondary to scar tissue from hernia repair 000006-625NUC-00013

Benign prostatic hypertrophy 000006-625NUC-00013

Severe osteoarthritis (left ankle) 000006-69AQG-00015

Acute bronchitis 000006-30HMA-00056-57

2002

Benign prostatic hypertrophy 000006-625NUC-00012

2003

Benign prostatic hypertrophy 000006-625NUC-00011

Groin pain from scar tissue from hernia repair 000006-625NUC-00011

Urinary tract infection 000006-625NUC-00011

History of chronic pain 000006-48CRSA-00005

Diverticulitis of sigmoid and lower descending colon 000006-64CMD-00071

Arthritis 000006-40VUM-00009

Lumbar strain 000006-69AQG-00006

Lumbar disc versus spinal stenosis 000006-30HMA-00062

Multilevel lumbar spinal stenosis (per MRI) 000006-53CAH-00003-4

L4-5 spondylolisthesis (per MRI) 000006-53CAH-00003-4

Lumbar spinal stenosis at L3-S1 with segmental instability 000006-33CMD-00084

Post-laminectomy syndrome 000006-30HMA-00063-64

Bilateral ankle pain with degenerative joint disease on left 000006-69AQG-00003

Anterior bony impingement (ankle) 000006-69AQG-00003

2003 (cont'd.)

Hyperpronation with early pes plano valgus (ankle) 000006-69AQG-00003

Basal cell carcinoma (tip of nose) 000006-39WBH-00023

Extruded suture after surgery (tip of nose) 000006-40VUM-00008

Retained suture with inflammation on nose 000006-40VUM-00010

Cataracts (both eyes) 000006-47LVC-00018

Rotator cuff tear (left shoulder) 000006-120PDS-00006

Osteoarthritis of the AC joint (left shoulder) 000006-120POS-00005

Probable rupture of long head of biceps (left arm) 000006-120POS-00006

2004

Pseudophakia (both eyes) 000006-47LVC-00010

Post-laminectomy syndrome (lumbar spine) 000006-42HMA-00097

Arthritic leg problems 000006-42HMA-00097

Spinal stenosis 000006-32TOA-00002-3

Sciatica 000006-32TOA-00004

Thoracic spine pain 000006-32TOA-00015-16

Essential hypertension, some related to stress 000006-42HMA-00089-90

Incomplete bony fusion lumbar spine at L4-5 (per myelogram) 000006-33TOA-00009

Degenerative changes lumbar spine, wrists and shoulders (per bone scan) 000006-20STH-00003

Acromioclavicular joint arthritis (shoulder) 000006-32TOA-00007

Fusion non-union at L4-5 with stenosis 000006-32TOA-00007

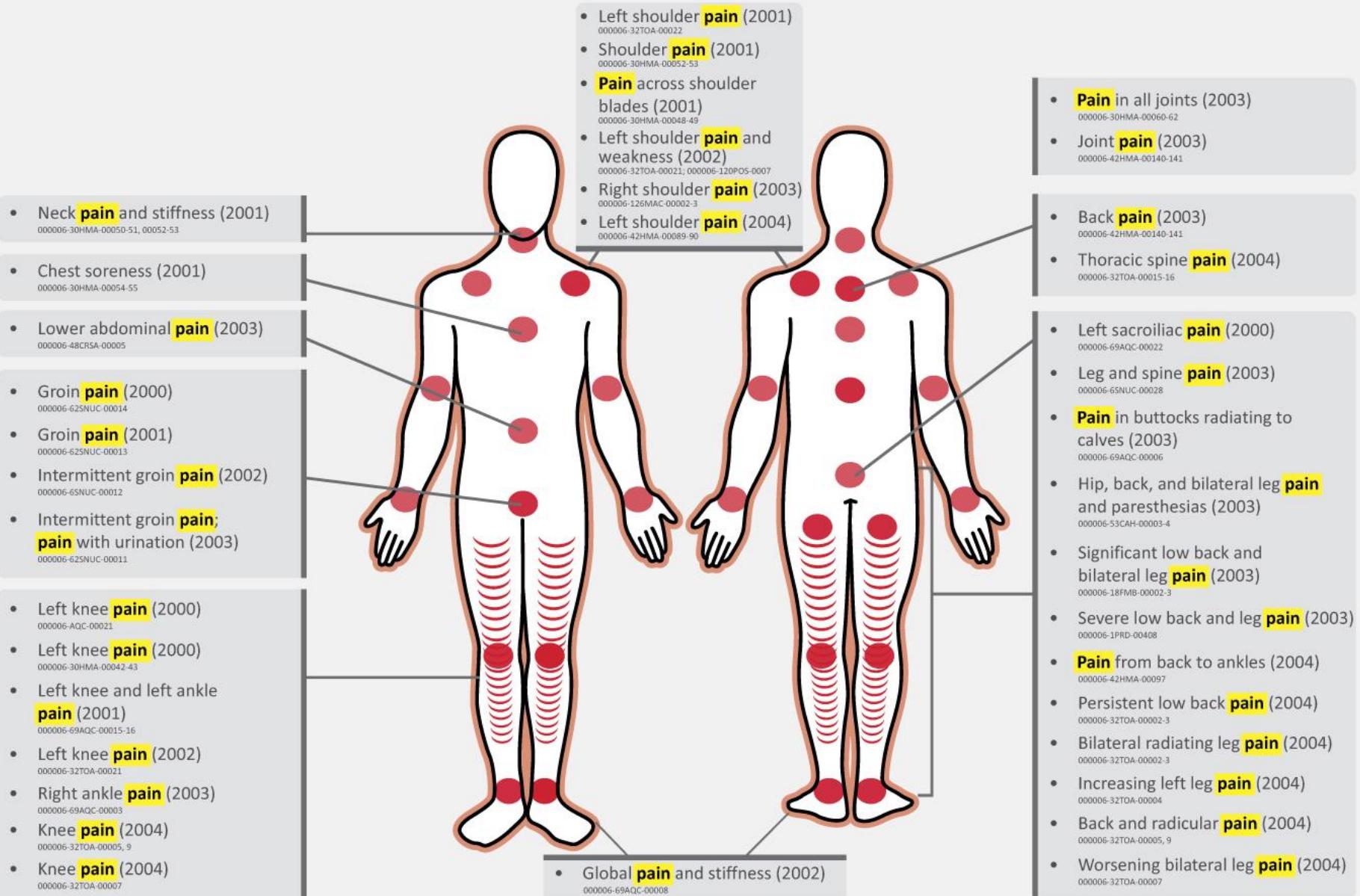
Mild demyelinating lumbar radiculopathy (per EMG) 000006-34NEA-00015-16

Bilateral L5 and S1 radiculopathy (per EMG) 000006-34NEA-00003

Mr. Smith's Diagnoses

1987	Diverticulitis 000006-48CRSA-00008	1992	Prostatic calcification 000006-625NUC-00024	1997	Diverticulitis 000006-48CRSA-00006	2001	Rotator cuff tear (left shoulder) 000006-32TOA-00022	2003 (cont'd.)	Hyperpronation with early pes plano valgus (ankle) 000006-69AQC-00003
1988	Benign prostatic hypertrophy with prostatic calcification 000006-625NUC-00027	Patellofemoral osteoarthritis (knee) 000006-69AQC-00072	Degenerative arthritis (both knees) 000006-69AQC-00073	Arthritic changes (lumbar spine and left hip) 000006-32TOA-00046	Degenerative joint disease (spine) 000006-30HMA-00048-49	Vertigo 000006-30HMA-00050-51	Basal cell carcinoma (tip of nose) 000006-39WBH-00023		
1989	Upper respiratory infection/otitis (left ear) 000006-42HMA-00215	Synovitis (left ankle) 000006-69AQC-00071	Severe osteoarthritis (left knee) 000006-69AQC-00071	Complete loss of articular cartilage (medial compartment of right knee) 000006-32TOA-00046	Degenerative joint disease 000006-30HMA-00050-51	Eustachian tube dysfunction; disequilibrium 000006-110AT-00001	Extruded suture after surgery (tip of nose) 000006-40VUM-00008		
	Bilateral ulnar nerve entrapment 000006-1PRD-00009	Degenerative joint disease (left knee) 000006-42HMA-00220	Musculoskeletal pain (left chest) 000006-1PRD-00002	Loss of bone stock (right knee) 000006-32TOA-00046	Degenerative arthritic changes (cervical spine) 000006-42HMA-00156	Groin pain secondary to scar tissue from hernia repair 000006-625NUC-00013	Retained suture with inflammation on nose 000006-40VUM-00010		
	Plantar fasciitis (right foot) 000006-69AQC-00077	Degenerative disease (right knee) 000006-69AQC-00077	Patellofemoral changes (right knee) 000006-32TOA-00046	Benign prostatic hypertrophy and chronic prostatitis 000006-625NUC-00018	Arthralgias, sleep disorder; questionable fibromyalgia 000006-30HMA-00052-53	Cataracts (both eyes) 000006-47LVC-00018			
		1994	Osteoarthritis (left ankle) 000006-69AQC-00064	1998	Herpes simplex virus I 000006-30HMA-00032-33	Eustachian tube dysfunction; disequilibrium 000006-110AT-00001	Rotator cuff tear (left shoulder) 000006-120PDS-00005		
1990	Benign prostatic hypertrophy and chronic prostatitis 000006-625NUC-00048-49	Folliculitis 000006-42HMA-00222	1995	Maxillary irritation 000006-1PRD-00023	Severe bladder neck contracture 000006-625NUC-00017	Groin pain secondary to scar tissue from hernia repair 000006-625NUC-00013	Osteoarthritis of the AC joint (left shoulder) 000006-120POS-00005		
	Acute iliopsoas strain (left hip) 000006-69AQC-00074	Muscular chest pain 000006-42HMA-00223		Severely symptomatic osteoarthritis (right knee) 000006-85BAH-00640-641	Benign prostatic hypertrophy 000006-625NUC-00012	Probable rupture of long head of biceps (left arm) 000006-120POS-00006			
		Recurrent left inguinal hernia 000006-30HMA-00072		Acid peptic disease, perhaps aspirin-related 000006-30HMA-00034-35	Severe osteoarthritis (left ankle) 000006-69AQC-00015				
		End-stage osteoarthritis (right knee) 000006-69AQC-00063		Lumbar spondylosis 000006-32TOA-00024	Acute bronchitis 000006-30HMA-00056-57				
		Patellofemoral disease 000006-69AQC-00063		Internal hemorrhoids 000006-48CRSA-00006	2002				
1991	Benign prostatic hypertrophy and chronic prostatitis 000006-625NUC-00048-49	1996	Severe osteoarthritis (right hip) 000006-69AQC-00062	Tendonitis (left shoulder) 000006-30HMA-00036-37	Benign prostatic hypertrophy 000006-625NUC-00015	2003			
			Complete loss of articular cartilage (right hip) 000006-69AQC-00061	Benign prostatic hypertrophy 000006-625NUC-00015	Benign prostatic hypertrophy 000006-625NUC-00011				
			Loss of bone stock (right hip) 000006-69AQC-00061	Acute chest pain/abdominal pain 000006-78BAH-00019	Groin pain from scar tissue from hernia repair 000006-625NUC-00011				
					Urinary tract infection 000006-625NUC-00011				
					History of chronic pain 000006-48CRSA-00005				
					Diverticulitis of sigmoid and lower descending colon 000006-64CMD-00071				
					Arthritis 000006-40VUM-00009				
					Lumbar strain 000006-69AQC-00006				
					Lumbar disc versus spinal stenosis 000006-30HMA-00062				
					Multilevel lumbar spinal stenosis (per MRI) 000006-53CAH-00003-4				
					L4-5 spondylolisthesis (per MRI) 000006-53CAH-00003-4				
					Lumbar spinal stenosis at L3-S1 with segmental instability 000006-33CMD-00042				
					Post-laminectomy syndrome 000006-30HMA-00053-64				
					Bilateral ankle pain with degenerative joint disease on left 000006-69AQC-00003				
					Anterior bony impingement (ankle) 000006-69AQC-00003				

Mr. Smith's Pain



Mr. Smith's Prescriptions



Advil

Use:
Nonsteroidal anti-inflammatory (NSAID)
Years Used:
1998, 2000, 2002, 2003, 2004



Amitriptyline

Use:
Tricyclic antidepressant (TCA)
Years Used:
2001, 2003



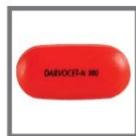
Bextra

Use:
Nonsteroidal anti-inflammatory (NSAID)
Years Used:
2004



Celestone

Use:
Steroid
Years Used:
2001-2002



Darvocet-N 100

Use:
Opioid/narcotic analgesic
Years Used:
1998-2001, 2003



Desipramine

Use:
Tricyclic antidepressant (TCA)
Years Used:
2003



Flexeril

Use:
Muscle relaxer
Years Used:
2000, 2003-2004



Ibuprofen

Use:
Nonsteroidal anti-inflammatory (NSAID)
Years Used:
2004



Lexapro

Use:
Antidepressant (SSRI)
Years Used:
2003



Lortab

Use:
Opioid/narcotic analgesic
Years Used:
2003-2004



Marcaine

Use:
Local anesthetic
Years Used:
2001-2002



Medrol

Use:
Steroid
Years Used:
2003



Mepergan Fortis

Use:
Narcotic analgesic/anti-nausea
Years Used:
2003



Naprosyn

Use:
Nonsteroidal anti-inflammatory (NSAID)
Years Used:
1999



Naproxen

Use:
Nonsteroidal anti-inflammatory (NSAID)
Years Used:
2001



Neurontin

Use:
Anti-epileptic (AED)
Years Used:
2004



Percocet

Use:
Opioid/narcotic analgesic
Years Used:
1998



Soma

Use:
Muscle relaxer
Years Used:
1998



Tylenol

Use:
Pain reliever
Years Used:
2003



Vioxx

Use:
Nonsteroidal anti-inflammatory (NSAID)
Years Used:
2000-2001, 2003

000006-69AQ-C-00006; 53CAH-00003-4; 33CMD-00025, 41, 42; 21ECD-00002; 30HMA-00010, 63-64, 65-66; 42HMA-00097, 151, 172, 186, 187; 34NEA-00001, 2, 3, 21; 1PRD-00124, 387, 408, 487; 62SNUC-00009, 32TOA-00002-3, 4; 35UMC-00062, 40VUM-00005-6, 9; 39WBH-00019; 120POS-00007

February 27, 2003

Neurological Surgeons Questionnaire

104-22145 - 112-N NEUROLOGICAL SURGEON NO. 914
 122-75 203 1-22PM NEUROLOGICAL SURGEON NO. 188 P. 5
NEUROLOGICAL SURGEON
 New Patient Medical Questionnaire 1084
 It is important for you to completely complete it, but if you need a doctor to do it, please let him or her do it.
 Name: Richard H. Smith, Jr., M.D. MD#2224472, SSN #24-3668
 Address: 1045 - Park Ave., Nashville, TN 37214, Charter
 Referring Doctor and address: Samuel Cato - Orthopaedic Assoc., 3701 N.
 Doctor you are seeing: Cato Hospital Today's date: 2/27/03
 Do you have a leg cast? No Do you have an anterior decompression? Yes No
 If yes, how long will it last? 4 weeks Do you have an anterior decompression? Yes No
 If yes, how long will it last? 4 weeks
 Present Problem:
 1. What complaint(s) why are you seeing the Doctor today? Please describe your symptoms and length of time you have had them.
 Sense pain in big artery down back of thigh, where Colon, into muscle above, head down, out at spine
 Tingling & hard to walk
 Trick to open bowels under pressure in anterior back, last 8 weeks
 2. Have you had the problem before? Yes Date: 1-22-03 How long? 8 weeks

, V.A. 22-75 1-22PM NEUROLOGICAL SURGEON NO. 914 P. 11
 122-75 203 1-22PM NEUROLOGICAL SURGEON NO. 188 P. 8
 1084-9404
 Migraine headaches
 Frequent episodes of joint pain Anesthesia last 8 weeks - Even in replaced joints
 Severe back pain
 Cut or leg pain with walking
GENERAL
 Blotches or bruises easily
 Any change in mood Depressed because of pain + lack of sleep
 Trouble sleeping With 4 am casts goes on. Hydrocodone
 Enclosed are your test results.

Any change in mood Depressed because of pain + lack of sleep

Heart disease						
High blood pressure	X	X				
Stroke						
Kidney disease						
Breast cancer			X		X	
Prostate cancer						
Colon cancer	X					
Psychiatric illness						
Anemia						

Social History
 Do you use tobacco? No How much and how long? _____
 Do you use alcohol? No How much and how long? _____
 Education? High school Part-time
 Vocational? Repos office equipment Bill working? Retired
 Are you exposed to toxins? No
 Physician's Signature: OT Date: 2/27/03

HIGHLY CONFIDENTIAL 000006-1PRD-00165 SNETH_R_0000166

February 27, 2003

Dr. Berklaich's Notes

Dr. Berklaich - Hasker, Stan

SPINE QUESTIONNAIRE

Name Richard H. Smith Date 3/27/03
Date of Birth 1/14/25 Age 78
Social Security Number 412-24-6663

Referring Physician Dr. Howard - Orthopedic just today Right or Left Handed (Circle One)
Family Physician James Cato

Occupation / Job Description: _____

Describe current back or neck pain: lower back, buttocks, down both legs.
He gets calves, in legs
Symptoms started seriously 8 wks ago, sleep now weak - not - but

Your pain as it usually is:



78-B TLR - Weekly
Golby puller

Your pain at its least severe: 0 1 2 3 4 5 6 7 8 9 10
No Pain Unbearable Pain

Wants DR. CATO & Physical
Had a fertility ring getting last surgery.
Has developed diarrhea
2^o Anxiety & pain.

000006-52FMB-00041

March 5, 2003

Mrs. Smith Phone Call to Dr. Berklaich

NURSES NOTES

DATE Name Lichard Smith MR# 5101

3503- received a phone call from Mrs. Smith requesting that her husband be put back on the surgery schedule. She stated "I don't know what's wrong with Richard - he's in so much pain - I think he is out of his mind". He saw Dr. McCombs on Monday and we didn't even

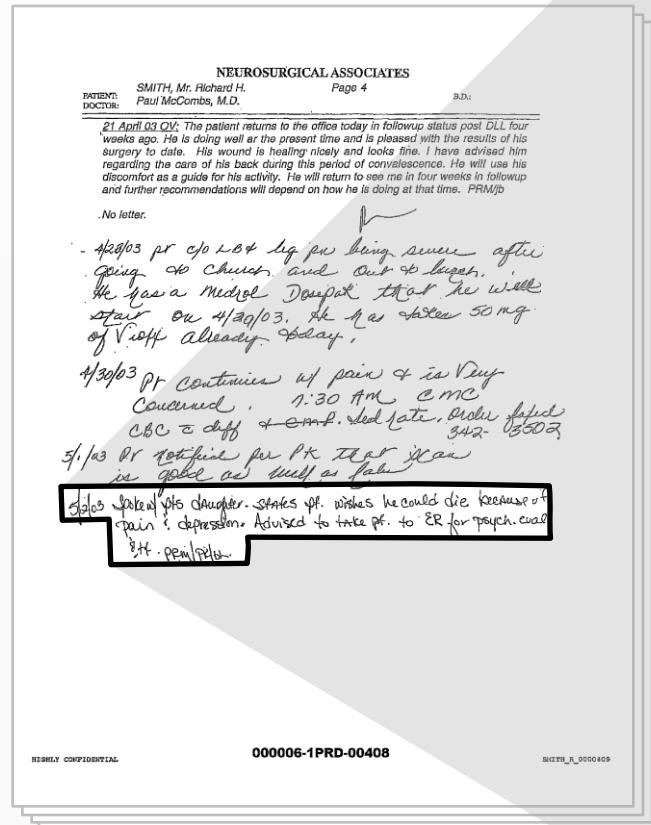
3503- received a phone call from Mrs. Smith requesting that her husband be put back on the surgery schedule. She stated "I don't know what's wrong with Richard - he's in so much pain - I think he is out of his mind".

Very concerned about canceling the surgery, even though had already been done. Explained to Mrs. Smith that I would talk to Dr. Nampf regarding the situation with Dr. Berklaich - Dr. Nampf regarding their feelings about proceeding with surgery. Will call them after speaking with them. Called Dr. Nampf's office and made them aware of this situation. Dr. Nampf's secretary will speak with him and let us know his feelings. Dr. White

000006-52FMB-00051

May 2, 2003

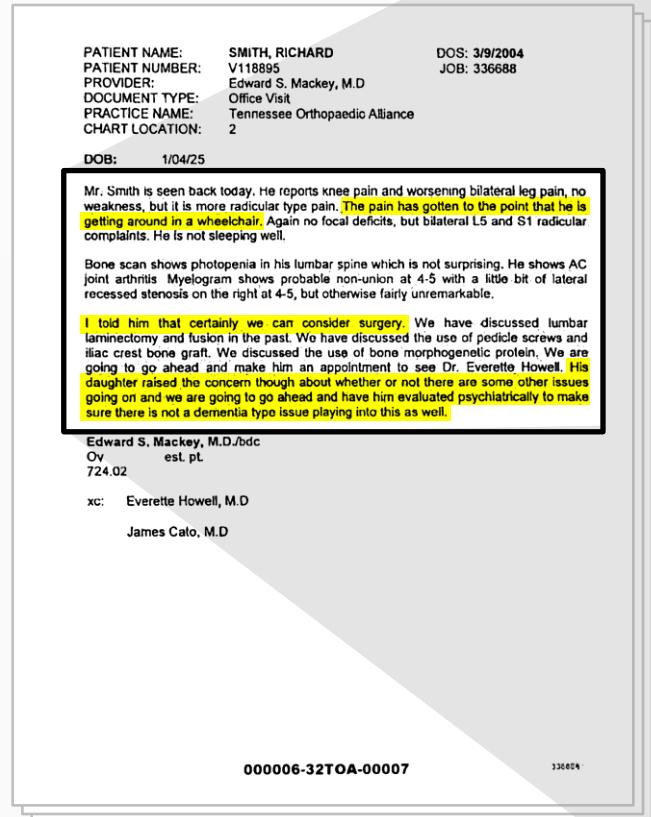
Neurosurgical Associates Notes – Dr. McCombs



Spoke w[ith] p[atiens]t's daughter. States p[atiens]t wishes he could die because of pain and depression. Advised to take p[atiens]t to ER for psych. eval and tx [treatment].

March 9, 2004

Dr. Mackey's Notes



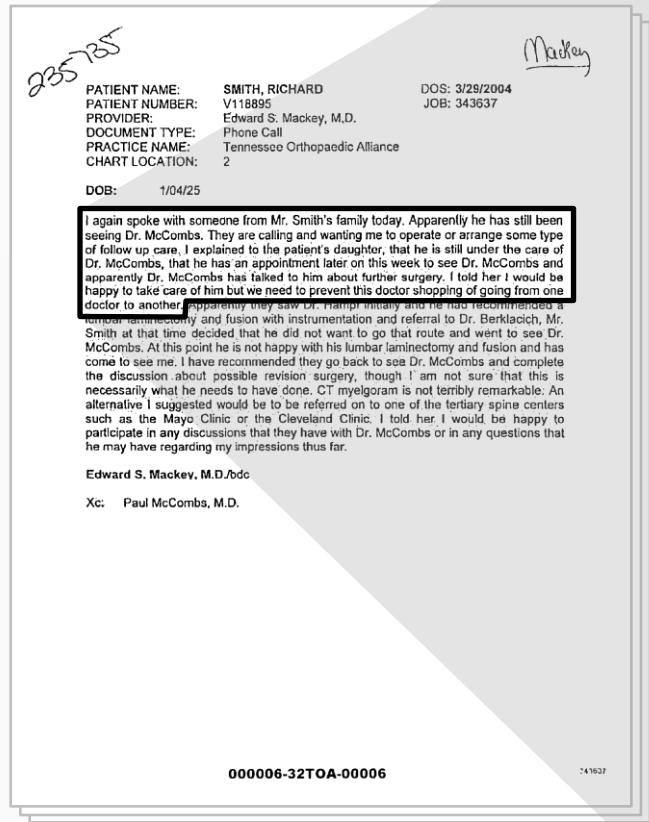
The pain has gotten to the point that he is getting around in a wheelchair.

* * *

I told him that certainly we can consider surgery. ... His daughter raised the concern though about whether or not there are some other issues going on and we are going to go ahead and have him evaluated psychiatrically to make sure there is not a dementia type issue playing into this as well.

March 29, 2004

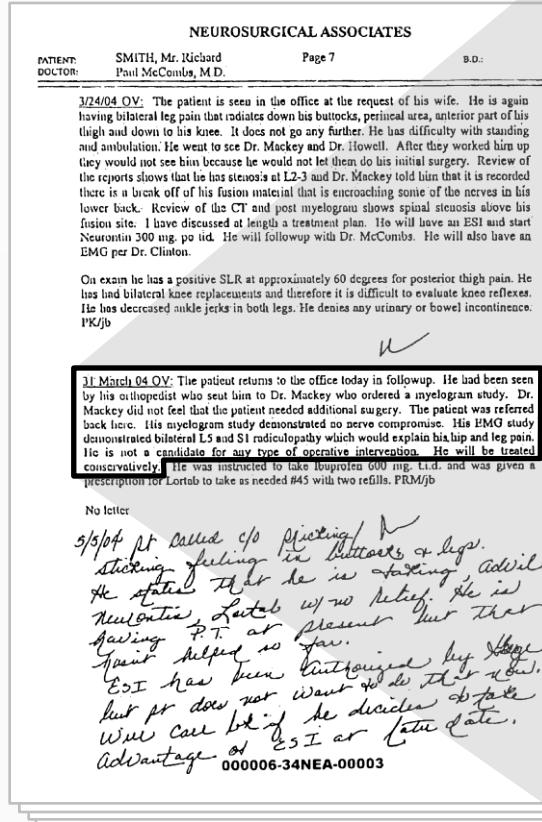
Dr. Mackey's Notes



I again spoke with someone from Mr. Smith's family today. ... I told her I would be happy to take care of him but we need to prevent this doctor shopping of going from one doctor to another.

March 31, 2004

Dr. McCombs's Notes



31 March 04 OV: ... He had been seen by his orthopedist who sent him to Dr. Mackey who ordered a myelogram study. Dr. Mackey did not feel that the patient needed additional surgery. The patient was referred back here. His myelogram study demonstrated no nerve compromise. His EMG study demonstrated bilateral L5 and S1 radiculopathy which would explain hip, hip and leg pain. He is not a candidate for any type of operative intervention. He will be treated conservatively. He was instructed to take Ibuprofen 600 mg. t.i.d. and was given a prescription for Lortab to take as needed #45 with two refills. PRM/jb

No letter

3/30/04 pt called c/o ~~picting~~ N
sticking feeling in buttocks & legs.
He states that he is taking advil;
he states that w/no relief. He is
newontics, Lortab w/o present but that
having P.T. at present but that
pain helped so far.
ESI has been authorized by ~~stage~~ Schenck
but pt does not want to do this now.
will call back if he decides to do it.
Advantage of ESI as late date.

000006-34NEA-00003

May 5, 2004

Dr. McCombs's Notes

NEUROSURGICAL ASSOCIATES		
PATIENT: DOCTOR:	SMITH, Mr. Richard Paul McCombs, M.D.	Page 7
B.D.:		
<p>3/24/04 OV: The patient is seen in the office at the request of his wife. He is again having bilateral leg pain that radiates down his buttocks, perineal area, anterior part of his thigh and down to his knee. It does not go any further. He has difficulty with standing and ambulation. He went to see Dr. Mackey and Dr. Howell. After they worked him up they would not see him because he would not let them do his initial surgery. Review of the reports shows that he has stenosis at L2-3 and Dr. Mackey told him that it is recorded there is a break off of his fusion material that is encroaching some of the nerves in his lower back. Review of the CT and post myelogram shows spinal stenosis above his fusion site. I have discussed at length a treatment plan. He will have an ESI and start Neurontin 300 mg. po tid. He will followup with Dr. McCombs. He will also have an EMG per Dr. Clinton.</p> <p>On exam he has a positive SLR at approximately 60 degrees for posterior thigh pain. He has had bilateral knee replacements and therefore it is difficult to evaluate knee reflexes. He has decreased ankle jerks in both legs. He denies any urinary or bowel incontinence. PRM/jb</p> <p>✓</p> <p>3/1 March 04 OV: The patient returns to the office today in followup. He had been seen by his orthopedist who sent him to Dr. Mackey who ordered a myelogram study. Dr. Mackey did not feel that the patient needed additional surgery. The patient was referred back here. His myelogram study demonstrated no nerve compromise. His EMO study demonstrated bilateral L5 and S1 radiculopathy which would explain his hip and leg pain. He is not a candidate for any type of operative intervention. He will be treated conservatively. He was instructed to take Ibuprofen 600 mg. t.i.d. and was given a prescription for Lortab to take as needed #45 with two refills. PRM/jb</p> <p>No letter</p> <p>5/9/04 pt called c/o Meeting ✓ sticking feeling in buttocks & legs. He states that he is taking advil; Neurontin, Lortab w/no relief. He is having PT at present but that hasnt helped so far. ESI has been authorized by George Schwab but pt does not want to do this now. Will call back if he decides to date. Advantage of ESI at later date. 600006-34NEA-00003</p>		

P[atient] called [complaining of] pricking/sticking feeling in his buttocks and legs. He states that he is taking Advil, Neurontin, Lortab w[ith] no relief. He is having [physical therapy] at present but that hasn't helped so far. ESI [Epidural Steroid Injection] has been authorized by George Schwab but p[atient] does not want to do that now. Will call b[ack] if he decides to take advantage of ESI at later date.

Pain has taken over my Mind & Body

I need Back Surgery

Left & Right Rotator Cuffs

Right Bicep Torn

Back Surgery to Correct Pain in Legs

Forgive me, I cannot go on like this!

I cannot have my body, the temple
of the Holy Spirit cut on anymore

I have talked to God almighty and

He understands,